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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/810,919 | 03/26/2004 | Thomas Wisniewski | 57953/1211 (2003-11-WIS02) | 9386 |
| 7590 Michael L. Goldman Nixon Peabody LLP Clinton Square P.O. Box 31051 Rochester, NY 14603-1051 | | | EXAMINER CHERNYSHEV, OLGA N | |
| | | | ART UNIT 1649 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/810,919 | Applicant(s) WISNIEWSKI ET AL. | |
| | Examiner Olga N. Chernyshev | Art Unit 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,8,9,12,19,20 and 27 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8,9,12,19 and 20 is/are rejected.
- 7) ☒ Claim(s) 5 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1, 5, 8, 12 and 19 have been amended, claims 4, 7, 15, 16 and 18 have been cancelled and claim 27 has been added as requested in the amendment filed on September 12, 2008. Following the amendment, claims 1, 5, 8-9, 12, 19-20 and 27 are pending in the instant application.

Claims 1, 5, 8-9, 12, 19-20 and 27 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on Sept 12, 2008 have been fully considered. The new grounds of rejections necessitated by amendments are set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 5, 8-9, 12, 19-20 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1 and 12, as currently amended, are vague and ambiguous for recitation of the substituted "residue 18" of SEQ ID NO: 3 because the protein of SEQ ID NO: 3 is only

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seventeen amino acids long. Amendment to recite residue 7 of SEQ ID NO: 3 or reference to position 18 of the original sequence of A β would obviate this ground of rejection.

7. Claims 5, 8-9, 19-20 and 27 are indefinite for being dependent from indefinite claims.

Claim Rejections - 35 USC § 102/103

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 8-9, 12 and 19-20, as amended, are rejected under 35 U.S.C. 102(b) as anticipated by Schenk et al. 1999, WO 99/27944 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schenk et al. 1999, WO 99/27944 in view of Sato et al., 1996 and Sato et al., US Patent 5,948,763 (IDS of 01/30/08, reference 2).

Claims 1, 8-9, 12 and 19-20 are directed to methods of treating AD by administration of an agent, which is an amyloid protein “comprising an amino acid sequence of at least 5 of the amino acids, in sequence, of SEQ ID NO:3, the protein including residue 18 of SEQ ID NO:3 and having an amino acid substitution of the valine at residue 18”. Document of Schenk teaches treatment of AD by administration of amyloid β peptides of different length, substitutions and modification, see reasons of record in the previous communication of record. Thus, the instant claimed method is fully encompassed and anticipated by Schenk even though Schenk document does not specifically recite the particular embodiments of the instant invention.

To establish anticipation or obviousness, it is important to determine the scope of the claimed subject matter and the content of the closest prior art. Rejection under 102/103 is justified when the reference teaches a small genus which places a claimed species in the

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possession of the public as in *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), and the species would have been obvious even if the genus were not sufficiently small to justify a rejection under 35 U.S.C. 102. See MPEP § § 2131.02 and 2144.08.

Specifically, MPEP 2131.02 states that

A GENERIC CHEMICAL FORMULA WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THE FORMULA WHEN THE SPECIES CAN BE “AT ONCE ENVISAGED” FROM THE FORMULA.

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990).

Further, in *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound. One of ordinary skill in the art would at once envisage the subject matter claimed within the reference.

In the instant case, document of Schenk describes genus of amyloid peptides, which is relatively limited due to the length of the amyloid peptide itself (43 amino acids max), so that the fragments and substituted species are easily envisaged by one of ordinary skill in the art.

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Moreover, the art at the time of invention teaches in details specific regions of A β (lipophilic, hydrophobic, more or less toxic, more prone to conformational changes, β -sheet breakers etc., see Applicant's cited art in IDS submissions and Sato et al. Patent in particular). Sato et al., 1998 reference (Nature Medicine, 1998, Vol. 4, 7, pp. 822-6), for example specifically describes the significance of the 17-20 region of A β and Proline substitutions within this region, which is the same region as encompassed by the subspecies of amyloid peptides recited in the instant claims. Thus, the subspecies of amyloid peptides covered by the instant invention can be easily envisaged by one of ordinary skill in the art and recognized within a relatively low genus of amyloid peptides disclosed by Schenk document and therefore, the reference of Schenk anticipates the instant claims or makes the claimed method obvious.

Allowable Subject Matter

13. Claims 5 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649